REMARKS

Claims 1-3, 5, 7, 8, 12-14, 16, 18, 19, 23, 26, 28, 31-34, 36, 38 and 39 were pending. Claims 1-3, 5, 7, 8, 12-14, 16, 18, 19, 32-34, 36, 38 and 39 have been canceled without prejudice.

New claims 52-56 have been added. These claims correspond to original claims 24, 25, 27, 29 and 30, each of which falls within the elected invention.

As a result, claims 23, 26, 28, 31 and 52-56 are now pending. No new matter has been added.

Rejections of the Claims Under 35 U.S.C. § 112

Enablement

The Examiner rejected claims 23, 28 and 31 as failing to comply with the enablement requirement of 35 U.S.C. § 112, first paragraph. Applicant respectfully traverses the rejection.

Applicant appreciates the Examiner's statement that the specification enables the claimed methods as they relate to several secretase pathway associated proteins. Applicant submits, however, that claims directed to methods related to the entire genus of secretase pathway associated proteins are enabled.

The Examiner stated that "one skilled in the art would have to reliably identify additional secretase pathway associated proteins such as those indicated in the art and then determine which, if any, of these proteins are stabilized by caspase activity" (Office Action, p.5) before the claimed methods could be practiced.

Applicant disagrees because the nature of the claimed invention, the guidance in the specification, the level of skill in the art, the state of the prior art and the quantity of

experimentation required all favor a finding that undue experimentation is not required to practice the claimed invention.

First, as the Examiner indicates on pages 4-5 of the Office Action, the prior art provides additional secretase pathway associated proteins in addition to those enumerated in the specification. Thus, the skilled person was familiar not only with the secretase pathway associated proteins listed in the specification, but also with other secretase pathway associated proteins. Therefore, the identification of additional secretase pathway associated proteins must be considered not to require undue experimentation.

Second, according to the claimed methods, cells that have been induced to undergo caspase activation are contacted with a candidate modulator of secretase pathway associated protein stabilization, and the stability of the secretase pathway associated protein is measured. The specification provides ample guidance for the step of inducing caspase activation in cells. Detemining whether a particular secretase pathway associated protein would be stabilized by caspase activation would be a relatively simple matter of testing the secretase pathway associated protein according to the claimed method with and without caspase activation. Furthermore, methods for determining the stability of a protein, such as a secretase pathway associated protein, were well known in the prior art. Therefore, the only a small and routine quantity of experimentation is required to determine if a particular secretase pathway associated protein is stabilized by caspase activation.

Thus based on the guidance in the specification, the level of skill in the art, the state of the prior art and the quantity of experimentation, the skilled person would not be required to undertake undue experimentation to practice the claimed invention throughout its scope.

Applicant therefore respectfully requests that the Examiner reconsider and withdraw the rejection of the claims under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

Written Description

The Examiner rejected claims 23, 28 and 31 as failing to comply with the written description requirement of 35 U.S.C. § 112, first paragraph. Applicant respectfully traverses the rejection.

The essence of Applicant's invention lies in the identification of the caspase activation-induced stabilization of secretase pathway associated proteins. This recognition permits the identification of compounds that modulate caspase activation-induced stabilization of a secretase pathway associated protein, as Applicant has claimed. The claimed methods are not limited to the particular secretase pathway associated proteins enumerated in the specification, because it is well within the capabilities of the person of ordinary skill in the art to make and test other secretase pathway associated proteins in order to identify compounds that modulate the disclosed stabilization.

The Examiner has noted publications that describe additional secretase pathway associated proteins. Thus, the skilled person knew of secretase pathway associated proteins in addition to those explicitly described in the specification, and could use these additional secretase pathway associated proteins in the claimed methods. Thus, the Examiner's statement on page 8 of the Office Action, that "[t]he general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed" appears to be incorrect.

According to Vas-Cath v. Mahurkar, the "applicant must convey with reasonable clarity to those skilled in the art that...he or she was in possession of the invention." Vas-Cath v. Mahurkar, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). In other words, the specification must "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." Id. at 1116. Based on the high level of knowledge of the skilled person and the disclosure of Applicant's specification, the skilled person would readily recognize that Applicant invented the claimed invention.

The written description requirement for sequences known in the art as recited in a claimed invention was recently addressed by the Federal Circuit in the case of Capon v. Eshhar v. Dudas (Fed. Cir., August 12, 2005). In that case, the court concluded that with respect to the sequences present in the claimed invention

> "... the law must take cognizance of the scientific facts. The Board erred in refusing to consider the state of the scientific knowledge, as explained by both parties, and in declining to consider the separate scope of each of the claims. None of the cases to which the Board attributes the requirement of total DNA re-analysis, i.e., Regents v. Lilly, Fiers v. Revel, Amgen, or Enzo Biochem, require a re-description of what was already known." Slip op. at 14.

The court continued:

> "The 'written description' requirement must be applied in the context of the particular invention and the state of the knowledge. The Board's rule that the nucleotide sequences of the chimeric genes must be fully presented, although the nucleotide sequences of the component DNA are known, is an inappropriate generalization. When the prior art includes the nucleotide information, precedent does not set a per se rule that the information must be determined afresh. Both parties state that a person experienced in the field of this invention would know that these known DNA segments would retain their DNA sequences when linked by known methods. Both parties explain that their invention is not in discovering which DNA segments are related to the immune response, for that is in the prior art, but in the novel combination of the DNA segments to achieve a novel result." Slip op. at 15.

The court concluded that:

> "In summary, the Board erred in ruling that §112 imposes a per se rule requiring recitation in the specification of the nucleotide sequence of claimed DNA, when that sequence is already known in the field." Slip op. at 20.

Similar to the applicants in Capon v. Eshhar v. Dudas, Applicant is claiming the use of sequences, in particular the use of such sequences in methods for identifying compounds.

The prior art, as acknowledged by the Examiner described secretase pathway associated protein sequences. Thus, one of ordinary skill in the art, having knowledge of secretase pathway associated proteins, would quite clearly recognize that Applicant was in possession of, and therefore had invented, the claimed methods.

All that is required for the specification to provide an adequate written description of the claimed invention is that the skilled person recognize that Applicant invented that which is now claimed. The Examiner stated that "the identity of the secretase pathway associated protein must be known in order to measure its stability and thereby use the [claimed] method." (Office Action at page 7). The Examiner's own citation of additional secretase pathway associated proteins in the prior art demonstrates that the skilled person was familiar with the identity of such proteins, and therefore could readily recognize that Applicant was in possession of the claimed method, as applicable to the entire genus of secretase pathway associated proteins.

Applicant therefore respectfully requests that the Examiner reconsider and withdraw the rejection of the claims under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

CONCLUSION

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,

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